DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST
829 TOWNE CENTER DR.
POMONA CA 91767

March 9, 2015

Re: K150275
Trade/Device Name: Immunalysis 6-acetylmorphine Urine Enzyme Immunoassay,
Immunalysis 6-acetylmorphine Urine Calibrator,
Immunalysis 6-acetylmorphine Urine Controls

Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, DKB, DIF
Dated: January 20, 2015
Received: February 4, 2015

Dear Mr. Ginete:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150275

Device Name
Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay, Immunalysis 6-Acetylmorphine Urine Controls and Immunalysis 6-Acetylmorphine Urine Calibrator

Indications for Use *(Describe)*
The Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 10ng/mL. The assay is intended for use in laboratories for the qualitative analysis of 6-Acetylmorphine in human urine with automated clinical chemistry analyzers. This assay is calibrated against 6-Acetylmorphine. This in-vitro diagnostic device is for prescription use only.

The Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunalysis 6-Acetylmorphine Urine Controls: The Immunalysis 6-Acetylmorphine Urine Controls are used as control materials in Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay.

Immunalysis 6-Acetylmorphine Urine Calibrator: The Immunalysis 6-Acetylmorphine Urine Calibrator is used as a calibrator in the Immunalysis Urine Enzyme Immunoassay for the qualitative determination of 6-Acetylmorphine in urine on automated clinical chemistry analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (K150275)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

A. Contact Information

1. Manufacturer:	Immunalysis Corporation
2. Contact Name:	Joseph Ginete
3. Contact Title:	Regulatory Affairs Specialist
4. Address:	829 Towne Center Drive Pomona, CA 91767
5. Phone:	(909) 482-0840
6. Fax:	(909) 482-0850
7. Email:	jginete@immunalysis.com
8. Summary prepared on:	March 6, 2015

B. Device Information

1. Trade Name:	Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay Immunalysis 6-Acetylmorphine Urine Controls Immunalysis 6-Acetylmorphine Urine Calibrator
2. Common Name:	Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay Immunalysis 6-Acetylmorphine Urine Controls Immunalysis 6-Acetylmorphine Urine Calibrator
3. Device Classification:	II
4. Regulation Number:	21 CFR 862.3650 Opiate Test System 21 CFR 862.3200 Clinical Toxicology Calibrator 21 CFR 862.3280 Clinical Toxicology Control Material
5. Panel:	Toxicology(91)
6. Product Code:	DJG DKB DIF

C. Legally Marketed Device to Which We are Claiming Equivalence (807.92(A)(3))

1. Predicate Device:	Emit® II Plus 6-Acetylmorphine Assay Emit® II Plus 6-AM/ Ecstasy Calibrators Emit® II Plus 6-AM/ Ecstasy Controls
2. Predicate Company:	Siemens Healthcare Diagnostics Inc.
3. Predicate K Number:	K102779

D. Device Description

The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes recombinant antibodies to 6-Acetylmorphine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in HEPES buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes 6-Acetylmorphine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in HEPES buffer with Sodium Azide as a preservative. Calibrator and controls are sold separately. Reagents are liquid, ready to use

The 6-Acetylmorphine calibrator and controls consist of a cutoff calibrator at 10ng/mL, a LOW control at 7.5ng/mL for the 10ng/mL cutoff and a HIGH control at 12.5ng/mL for the 10ng/mL cutoff.

E. Intended Use

The Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 10ng/mL. The assay is intended for use in laboratories for the qualitative analysis of 6-Acetylmorphine in human urine with automated clinical chemistry analyzers. This assay is calibrated against 6-Acetylmorphine. This in-vitro diagnostic device is for prescription use only.

The Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunalysis 6-Acetylmorphine Urine Controls: The Immunalysis 6-Acetylmorphine Urine Controls are used as control materials in Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay.

Immunalysis 6-Acetylmorphine Urine Calibrator: The Immunalysis 6-Acetylmorphine Urine Calibrator is used as a calibrator in the Immunalysis Urine Enzyme Immunoassay for the qualitative determination of 6-Acetylmorphine in urine on automated clinical chemistry analyzers.

F. Comparison of the new device with the predicate device

	6-Acetylmorphine Assay K102779	**Immunalysis 6-Acetylmorphine Urine EIA**
Intended Use	The qualitative analysis of 6-Acetylmorphine in human urine with automated clinical chemistry analyzers	Same
Type of Product	Analytical Reagents	Same
Measured Analytes	6-Acetylmorphine	Same
Test Matrix	Urine	Same
Cutoff Levels	10ng/mL of 6-Acetylmorphine	Same
Test System	Homogeneous Enzyme Immunoassay	Same
Materials	Liquid Ready-to-Use R1 Reagent and Lyophilized R2 Reagent	Liquid Ready-to-Use Antibody/Substrate Reagents and Liquid Ready-to-Use Enzyme Labeled Conjugate

	6-Acetylmorphine Assay K102779	Immunalysis 6-Acetylmorphine Urine EIA
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Same
Antibody	Mouse monoclonal antibody to 6-Acetylmorphine	Recombinant antibody to 6-Acetylmorphine
Storage	2 – 8°C until expiration date	Same
Calibrator Form	Liquid	Same
Calibrator Level	Four (4) Levels (5, 10, 15 and 20 ng/mL)	One (1) Level (10ng/mL)
Control Levels	Two (2) Levels (7.5 and 12.5ng/mL)	Same

G. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay to the predicate

1. Precision/Cutoff Characterization – Study was performed for 20 days, 2 runs per day in duplicate (N=80) on concentration of ±25%, ±50%, ±75%, and ±100% of the cutoff. The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. In addition, it also verified product performance relative to the ability of the device to produce the same value during repeated measurements. The instruments used for this was Beckman Coulter AU 400e.

   The following is a summary table of the Qualitative Analysis for the 10ng/mL cutoff test data results.

Table 1 - Qualitative Analysis (for 10ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
2.5	-75%	80	80 Negative
5	-50%	80	80 Negative
7.5	-25%	80	80 Negative
10	Cutoff	80	43 Neg / 37 Pos
12.5	+25%	80	80 Positive
15	+50%	80	80 Positive
17.5	+75%	80	80 Positive
20	+100%	80	80 Positive

2. Specificity and Cross-Reactivity – Structurally similar compounds were spiked into drug free urine at levels that will yield a result that is equivalent to the cutoff. The instrument used for this test was a Beckman Coulter AU 400e.

   The qualitative result summary table for the 10ng/mL cutoff is outlined below:

Table 2 - Structurally Related Compounds (for 10 ng/mL cutoff) - Qualitative

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
6-Acetylmorphine	10	Positive	100
6-Acetylcodeine	600	Positive	1.7
Buprenorphine	1,000,000	Negative	N.D.
Codeine	1,000,000	Negative	N.D.
Dextromethorphan	1,000,000	Negative	N.D.
Dihydrocodeine	1,000,000	Negative	N.D.

Table 2 - Structurally Related Compounds (for 10 ng/mL cutoff) - Qualitative			
Ethylmorphine	1,000,000	Negative	N.D.
Heroin	1,375	Positive	0.7
Hydrocodone	1,000,000	Negative	N.D.
Hydromorphone	325,000	Positive	0.003
Imipramine	1,000,000	Negative	N.D.
Levorphanol	1,000,000	Negative	N.D.
Meperidine	1,000,000	Negative	N.D.
Morphine	285,000	Positive	0.000035
Morphine 3-D-glucuronide	1,000,000	Negative	N.D.
Morphine 6-D-glucuronide	1,000,000	Negative	N.D.
Nalorphine	80,000	Positive	0.0125
Naloxone	300,000	Positive	0.00333
Naltrexone	390,000	Positive	0.00256
Naproxen	1,000,000	Negative	N.D.
Norbuprenorphine	100,000	Negative	N.D.
Norcodeine	1,000,000	Negative	N.D.
Normorphine	250,000	Positive	0.004
Oxycodone	1,000,000	Negative	N.D.
Oxymorphone	360,000	Positive	0.00277

3. Interference – Structurally non-similar compounds, endogenous compounds, the effect of pH and the effect of specific gravity was evaluated by spiking the potential interferent into drug free urine containing the target analyte at ±25% of the cutoff. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the structurally non-similar compounds for the 10ng/mL cutoff :

Table 3 - Structurally Non-Similar Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (7.5ng/mL)**		**+25% Cutoff (12.5ng/mL)**	
		Result	Interference?	Result	Interference?
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicyclic Acid	500,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflurnitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
S-(+) Amphetamine	100,000	Negative	No	Positive	No
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Chlorpromazine	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No

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Table 3 - Structurally Non-Similar Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
Cocaine	100,000	Negative	No	Positive	No
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Desalkyflurazepam	100,000	Negative	No	Positive	No
Dehydronorketamine	50,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Delta-9-THC	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
N-desmethyltapentadol	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Diphenhydramine	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
Ecgonine	100,000	Negative	No	Positive	No
Ecgonine methyl ester	100,000	Negative	No	Positive	No
EDDP	100,000	Negative	No	Positive	No
1R,2S(-)-Ephedrine	100,000	Negative	No	Positive	No
1S,2R(+)-Ephedrine	100,000	Negative	No	Positive	No
Ethyl glucuronide	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fentanyl	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
11-hydroxy-delta-9-THC	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrignine	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
(+)-MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Methadone	100,000	Negative	No	Positive	No
S(+)-Methamphetamine	100,000	Negative	No	Positive	No
Methaquolone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylphenidate	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No

Table 3 - Structurally Non-Similar Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
Nitrazepam	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxazepam glucuronide	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Proproxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R(-)-Pseudoephedrine	100,000	Negative	No	Positive	No
S,S(+)-Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
11-nor-9 carboxy THC	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No
Verapamil	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

b. The following is a summary table of the endogenous compounds results for the 10ng/mL cutoff:

Table 4 - Endogenous Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	**1.5 g/dL**	**Negative**	**No**	**Negative**	**Yes**
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No

Table 4 - Endogenous Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.115 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	**6.0 g/dL**	**Negative**	**No**	**Negative**	**Yes**
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

c. The following is a summary table of the additional ascorbic acid and sodium chloride testing at ±50% of the cutoff:

Table 5 - Endogenous Compounds (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-50% Cutoff (5ng/mL)		+50% Cutoff (15ng/mL)	
		Result	Interference?	Result	Interference?
Ascorbic Acid	**1.5 g/dL**	**Negative**	**No**	**Negative**	**Yes**
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No

d. The following is a summary table of Boric Acid for the 10ng/mL cutoff results:

Table 6 – Boric Acid (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	**Negative**	**No**	**Negative**	**Yes**

e. The following is a summary table of the additional boric acid testing at ±50% of the cutoff:

Table 7 – Boric Acid (for 10ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-50% Cutoff (5ng/mL)		+50% Cutoff (15ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	**Negative**	**No**	**Negative**	**Yes**

f. The following is a summary table of the effect of pH results for the 10ng/mL cutoff:

Table 8 - Effect of pH (for 10ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (7.5ng/mL)		+25% Cutoff (12.5ng/mL)	
		Result	Interference?	Result	Interference?
pH	**3.0**	**Negative**	**No**	**Negative**	**Yes**
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

g. The following is a summary table of the additional pH 3.0 testing at ±50% of the cutoff:

Table 9 - Effect of pH (for 10ng/mL cutoff)					
Test Parameter	Value	**-50% Cutoff (5ng/mL)**		**+50% Cutoff (15ng/mL)**	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No

h. The following is a summary table of the effect of specific gravity results for 10ng/mL cutoff:

Table 10 - Effect of Specific Gravity (for 10ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (7.5ng/mL)**		**+25% Cutoff (12.5ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	No

i. Ascorbic acid, sodium chloride, boric acid and pH of 3 are considered interferences

4. Method Comparison – Unaltered, anonymous and discarded clinical urine samples obtained from clinical testing laboratories were analyzed with the test device. The study verified that the product performance can be verified by Mass Spectrometry. The instrument used for this test was a Beckman Coulter AU 400e and an Agilent 6430 Liquid Chromatography Tandem Mass Spectrometry.
   a. The following is a comparison table of qualitative assay performance for the 10ng/mL cutoff:

Table 11 - Method Comparison (for 10ng/mL cutoff) - Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

b. The following is a summary table of qualitative assay performance for the 10ng/mL cutoff:

Table 12 - Assay Performance verified by LC/MS – 10ng/mL Cutoff					
Type	6-Acetylmorphine Concentration				Agreement (%)
	< 5ng/mL	5.0 ~ 9.9 ng/mL	10 ~ 15 ng/mL	> 15 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

5. Stability –
   A closed accelerated stability study was performed on reagents, calibrator and controls at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year for reagents. This stability study supported an initial expiration date of 12 months for calibrator and controls. The instrument used for this test was a Beckman Coulter AU 400e. Real stability studies are ongoing.
6. Calibrator and Control Traceability – all components of the calibrator and controls have been traced to a commercially available standard solution.
7. Calibrator and Control Stability – An open accelerated stability study was performed at 25ºC to establish the initial open vial expiration dating. The stability

study supported an initial open vial expiration date of 12 months. The instrument used for this test was a Beckman Coulter AU 400e. All calibrator level(s) (10ng/mL) and control level(s) (7.5ng/mL and 12.5ng/mL) were within specifications for Day 0, 2, 8, 16, 24, 30, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.

8. Calibrator and Control Value Assignment – calibrator and controls are manufactured and are tested by mass spectrometry. If any of the analytes are out of the acceptable range, then the calibrator and control is adjusted and re-tested. Values are assigned to the calibrator and controls once the mass spectrometry results are within the acceptable ranges.

H. Conclusion

The information provided in this pre-market notification demonstrates that the Immunalysis 6-Acetylmorphine Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use.